IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXACT SCIENCES CORPORATION, Plaintiff, v. GENEOSCOPY, INC., Defendant.	Civil Action No. 23-1319-MN

REPLY BRIEF IN SUPPORT OF DEFENDANT GENEOSCOPY, INC.'S MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

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For the reasons set forth in Geneoscopy's Opening Brief (D.I. 19) and discussed further below, the Court should dismiss Exact's First Amended Complaint ("FAC") in its entirety.

ARGUMENT

A. Exact's Claim for Past Infringement Fails as a Matter of Law.

Exact attempts to distinguish cases in this District dismissing declaratory judgment actions directed to future infringement on the ground that Exact also alleges past infringement.[1] D.I. 23 ("Opp.") 5-6. But Exact's implausible claim of past infringement fails to meet the Rule 12(b)(6) pleading standard and must be dismissed as a matter of law. It is black letter law that an alleged offer for sale or sale of Geneoscopy's ColoSense kit cannot establish infringement of the ***methods*** claimed in the '781 patent. Indeed, Exact acknowledges this Court's holding that offering to sell or selling a method does not constitute infringement under § 271.[2] Opp. 9.

Unable to overcome directly adverse case law, Exact pivots to characterizing its pleading as also alleging that Geneoscopy has commercially ***used*** the claimed methods. Opp. 8. Yet no allegation it cites supports this claim. The first allegation cited is that Geneoscopy has "***used*** . . . the ColoSense product." *Id*. But, once again, the '781 patent claims methods, not products. The next allegation is that Geneoscopy "developed" ColoSense to compete with Cologuard using the fecal sample processing methods claimed in the '781 patent. *Id.* (quoting FAC ¶ 67). But the FAC makes allegations about the ***design*** of ColoSense, it does not allege that any patient has actually performed the processing methods claimed in the '781 patent. Next, Exact quotes

[1] *E.g., Juno Therapeutics, Inc. v. Kite Pharma, Inc*., C.A. No. 16-1243-RGA, 2017 U.S. Dist. LEXIS 90445 (D. Del. June 13, 2017); *Clarus Therapeutics, Inc. v. Lipocine, Inc*., C.A. No. 15-1004-RGA-MPT, 2016 U.S. Dist. LEXIS 138772, at *5-6 (D. Del. Oct. 6, 2016).

[2] The Court should reject Exact's invitation to revisit its prior holdings, which follow the Federal Circuit and other courts. *E.g., Joy Techs. Inc. v. Flakt, Inc*., 6 F.3d 770, 773 (Fed. Cir. 1993) ("The law is unequivocal that the sale of equipment to perform a process is not a sale of the process within the meaning of 271(a).").

language from paragraph 68 of the FAC that merely parrots the words of § 271(a) and again refers to Geneoscopy's ***products***, not to the claimed methods. These conclusory allegations do not plausibly allege that a ***patient*** (not Geneoscopy) collected, separated, and processed a fecal sample at home, as required by the patent. Finally, Exact's reference to its claim chart, drawn from Geneoscopy's clinical trial protocol, only underscores Exact's inability to allege any actual past infringement outside the protection of the Hatch-Waxman safe harbor.

B. The Court Lacks Jurisdiction Over Exact's Declaratory Judgment Claim.

Lacking any viable claim of past infringement, Exact is left with its premature claim for a declaratory judgment that Geneoscopy "will infringe" upon FDA approval. This allegation is insufficient to establish an Article III case or controversy and the claim must be dismissed.

As a threshold matter, Exact ignores controlling law that subject matter jurisdiction must be determined as of the date of filing of the complaint. *Microsoft Corp. v. DataTern, Inc.,* 755 F.3d 899, 906 (Fed. Cir. 2014) ("[P]ost-complaint facts cannot create jurisdiction where none existed at the time of filing."); *Benitec Austl. Ltd. v. Nucleonics, Inc*., 495 F.3d 1340, 1344 (Fed. Cir. 2007). Under this rule, even if FDA approval comes tomorrow, next month, or prior to resolution of this motion, it would have no effect on this Court's jurisdiction. Notably, Exact's original complaint filed in November 2023 alleged that FDA approval was then "imminent" (D.I. 1 ¶ 64), yet more than four months have passed since then and no such approval has occurred, underscoring that the predicate for jurisdiction cannot be founded on speculation.[3]

Adhering to the jurisdictional rule also makes sense as a matter of judicial economy. Without FDA approval of ColoSense and its accompanying label and instructions for use, "any

[3]Many of the statements by Geneoscopy employees on which Exact now relies were made ***after*** November 17, 2023, when suit was commenced. Such statements must be disregarded, because they are not relevant to the existence of subject matter jurisdiction on the date Exact filed suit.

judicial determination as to whether [the product] could infringe the method claims would constitute an advisory opinion." *Amarin Pharms. Ireland Ltd. v. Omthera Pharms., Inc.*, No. 14-791-GMS, 2014 U.S. Dist. LEXIS 205700, at *4 (D. Del. Nov. 14, 2014).

Moreover, even if FDA approval were imminent, Exact's claims are not ripe where the timeframe for actual commercial launch by Geneoscopy is uncertain. *Id.* (dismissing declaratory judgment claim despite FDA approval where "the product's launch date remains uncertain, [and] any potential future infringement is not sufficiently immediate"). Exact misstates its own allegations when it argues that "the FAC alleges Geneoscopy has repeatedly stated that it is prepared to immediately launch ColoSense upon FDA approval." Opp. 8. The FAC says no such thing. Rather, the FAC cites statements of Geneoscopy employees regarding the hoped-for timing of ***FDA approval***, without indicating any timeline for launch. Exact's citation to a press release regarding a Labcorp agreement does not alter the analysis. That press release merely describes Labcorp's agreement to distribute ColoSense at an unspecified time ***after*** FDA approval (not before). D.I. 15, Ex. T. Exact has presented no evidence that ColoSense will launch "immediately" after approval, and Geneoscopy has no plans to do so.

Exact's caselaw does not support its arguments. *Cephalon, Inc. v. Sandoz, Inc*., No. 11-821-SLR, 2012 U.S. Dist. LEXIS 26494 (D. Del. Mar. 1, 2012), is inapposite. That case addressed whether jurisdiction had been triggered as to two of four asserted patents under § 271(e)(2) where Sandoz had filed an ANDA but had not amended its Orange Book certification. *Id*. at *19 (concluding that unless the court could exercise jurisdiction over all four Orange Book-listed patents, the ANDA filer "would be given an advantage not contemplated under the careful balancing act of [Hatch-Waxman], to wit, the ability to market its generic as soon as its ANDA is approved by the FDA without responsibly resolving all the patent issues

related to said product"). Moreover, "'[t]here is a significant difference, both in terms of timing and certainty, between the ANDA approval process and the process of obtaining approval of a BLA' or an NDA." *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, C.A. No. 17-12087-ADB, 2018 U.S. Dist. LEXIS 233075 at *24 (D. Mass. Sept. 27, 2018). The *Teva* court, like the Delaware courts in *Juno* and *Clarus*, dismissed the declaratory judgment action before it for lack of jurisdiction and underscored Congress's intent to facilitate pre-approval patent litigation only in connection with ANDA/aBLA submissions.

Exact's reliance on *Allergan, Inc. v. Revance Therapeutics, Inc.*, No. 21-1411-RGA, 2022 U.S. Dist. LEXIS 129397 (D. Del. July 21, 2022), is equally misplaced. As Exact acknowledges, Opp. 6, the *Allergan* court distinguished *Juno* and *Clarus* because in *Allergan* there were plausible claims of past infringement. That distinction cannot save Exact here. Moreover, in *Allergan*, the accused infringer conceded that it was manufacturing and stockpiling the accused product for commercial launch—activities falling outside the safe harbor. Lastly, in *LifeScan Scotland Ltd. v. Shasta Techs., LLC*, No. 11-CV-04494 EJD, 2012 U.S. Dist. LEXIS 100549, *3-4 (N.D. Cal. July 19, 2012), not only were defendants stockpiling the accused product, they also had announced a specific timetable for commercial launch and had accepted pre-orders. Exact has not met its burden of establishing this Court's jurisdiction.

C. The Court Should Dismiss Exact's Lanham Act Count in View of the FDA's Primary Jurisdiction Over Evaluating the Safety and Effectiveness of Drugs and Medical Devices.

In disputing the FDA's primary jurisdiction over the scientific validity and interpretation of Geneoscopy's clinical data, Exact asserts there is "no basis" for this Court to conclude that Exact made "prior application to the [FDA]" concerning those issues. Opp. 13. But Exact does not deny that on January 12, 2024, it filed a First Amended Complaint disclosing its prior filing with the FDA of a "Trade Complaint Regarding Geneoscopy Inc.'s Promotion of Colorectal

Cancer (CRC) Screening Test and Violations of the Federal Food, Drug and Cosmetic Act." D.I. 21, Ex. 3 at 67 n.93. Nor does Exact deny (as the title of the complaint suggests) that its pending FDA trade complaint raises the same issues it alleges here: that Geneoscopy's clinical data supporting its PMA are "unreliable" and do not establish the safety and effectiveness of ColoSense, and that Geneoscopy is improperly promoting ColoSense using comparative advertising. Exact cannot avoid dismissal by pretending that it made no prior application to the FDA raising these issues. The Court has ample basis to infer otherwise, and Exact cannot survive a motion to dismiss by concealing jurisdictional facts.

Exact's arguments concerning the other *Baykeeper* factors likewise do not withstand scrutiny. The question is not whether hypothetically a plaintiff could allege a false advertising claim falling outside the FDA's special expertise: it is whether Exact did so here. Unlike the cases Exact cites, here Exact's allegations challenge the scientific validity and reliability of the clinical data submitted to the FDA to support approval.[4] Exact states that the FDA will only evaluate whether Geneoscopy's data establish that ColoSense is safe and effective, not whether Geneoscopy's statements harm Exact. But the premise of Exact's allegation of harm is that the data are invalid and unreliable, questions the FDA itself evaluates when it determines safety and efficacy. A judicial finding that Geneoscopy's public statements were false, misleading, and

[4] In *G&W Labs.,* plaintiff alleged that defendant's statements that its drug was equivalent to or substitutable for plaintiff's drug were literally false. This was not a question presented to the FDA, nor did plaintiff challenge the validity of any data submitted to the FDA. Exact also overlooks that in *G&W Labs* the court cited the FDA's primary jurisdiction to dismiss several other false advertising claims purporting to raise technical issues about defendant's drug. In *Cipla*, the false advertising claim concerned public statements about a product's HPCPS reimbursement code; the court found that the claim did not usurp any agency authority. In *Caldon*, plaintiff's false advertising claim was based on defendant's submission of false information to the agency, which is not alleged here. Finally, in *CareDx*, defendant's product did not require FDA approval and thus the primary jurisdiction doctrine was not before the court.

harmful to Exact, when they merely referenced data reported in *JAMA*, would directly conflict with an FDA finding that the study's conclusions were clinically valid. And if the FDA so concludes (having formed its judgment that the data are not false and misleading), then any supposed "harm to Exact Sciences" (Opp. 11) is not actionable, and no forum need evaluate it.

In short, whether the data reported in *JAMA* are sufficiently reliable to establish the safety and effectiveness of ColoSense are questions for the FDA. 21 U.S.C. §360c(a)(C) & 360(e); 21 C.F.R. pt. 814. These are scientific judgments that experienced FDA scientists and statisticians make daily; there can be no serious disagreement that evaluating the validity of Geneoscopy's study parameters and clinical data falls squarely within the realm of the FDA's special expertise.

Exact's insistence that the Court conduct a trial to independently evaluate the validity of Geneoscopy's clinical data would dramatically expand the Lanham Act, inviting competitors to challenge the FDA's past approval of drugs and devices under the guise of false advertising claims. If Exact's theory were accepted, any manufacturer could contest the FDA's approval of a competing drug or device simply by alleging that the competitor's registration trial relied on flawed methodology, a too-small patient population, or some other alleged defect, and claim on that basis that the competitor's public statements referencing its phase III clinical data constitute false advertising. This far-reaching extension of the Lanham Act would upset the carefully calibrated regulatory scheme created by the FD&C Act, have a chilling effect on investment in health care, and jeopardize patients' access to new life-saving medical devices and drugs.

D. Exact Lacks Standing Under the Lanham Act.

Exact does not and cannot allege that the statements made by Geneoscopy proximately cause injury to Exact. Because Exact is unable to identify any actual harm caused by Geneoscopy's statements, it contends it need only plausibly allege that the statements will *likely* cause harm. Opp. 14. Exact fails to meet this burden. Relying heavily on *CareDx, Inc. v. Natera,*

Inc., C.A. No. 19-662-CFC-CJB, 2019 U.S. Dist. LEXIS 219451(D. Del. Dec. 20, 2019), Exact claims that allegations of potential lost future sales can constitute proximate cause. But in *CareDx*, defendant Natera's competing product did not require FDA approval,[5] allowing Natera to "actively advertis[e]" and "market[]" the product to "major clinical centers" while "in the midst of launching" it commercially. *Id.* at *17. Here, by contrast, Geneoscopy's ColoSense product does require regulatory approval, and Geneoscopy was not actively advertising or marketing its product to clinical centers while in the midst of launching the product at the time of the alleged false advertising.

Unless and until the FDA approves ColoSense, any alleged harm in this case is speculative. *See Ortho Pharm. Corp. v. Cosprophar, Inc.*, 828 F. Supp. 1114, 1125 (S.D.N.Y. 1993) (holding plaintiff had no standing because "the parties here do not 'compete' in any market, because Ortho is barred by federal law from promoting RETIN-A for anti-wrinkle use"). Tellingly, Exact does not point to a single case in which a Lanham Act claim was successfully pursued against a defendant requiring regulatory approval for a product not yet on the market. The speculative nature of Exact's alleged future harm distinguishes this case from *CareDx* and makes it more like the cases courts dismissed for lack of standing because no competing product was on the market. *See PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1112 (2d Cir. 1997); *Alphamed Pharms. Corp. v. Arriva Pharms., Inc.*, 391 F. Supp. 2d 1148, 1163-64 (S.D. Fla. 2005). Exact's conclusory allegations of harm do not suffice to create standing.

[5] *See* https://www.natera.com/company/news/natera-launches-prospera-kidney-with-quantification-to-further-improve-test-performance-demonstrating-commitment-to-innovation-in-transplantation-2/

E. Exact Fails Plausibly to Allege Required Elements of a Lanham Act Claim.

Exact's false advertising claim must also be dismissed because Exact has not plausibly pled the necessary elements of its Lanham Act claim.

Alleged false and misleading statements. Exact concedes that the *JAMA* Report itself does not contain any false or misleading statements. Opp. 17 ("Although the FAC contains a detailed discussion of the failings of the Barnell Study . . . it does so to support the allegations that Geneoscopy's advertising claims 'are not established by the Barnell Study or any other published study on ColoSense.'"). But as explained in Geneoscopy's opening brief, every statement Exact challenges either references, quotes, or identifies data reported in *JAMA* as the source. The one example Exact cites of an allegedly "false and misleading" statement about Geneoscopy's clinical study is Geneoscopy's "claim[] of '100% CRC sensitivity'" in the 45-49 age group on the ground that it does so without "disclosing that the study only analyzed five cancers" in that group. Opp. 17. But the *JAMA* Report itself discloses the number of patients in the 45-49 age cohort who had colorectal cancer. FAC, Ex. D at 1764.[6] Most of Exact's allegations are that Geneoscopy's statements about the Report lacked (not misrepresented) what Exact views as necessary detail. Yet any interested reader who might be influenced by that level of detail could readily locate and review the Report and the three supplements linked to it that contain the supporting data. Accurate statements reporting the results of a scientific study are not actionable under the Lanham Act. *See* Opening Br. 15-16.

Exact also alleges that Geneoscopy made false and misleading "superiority claims" by citing the *JAMA* Report's data showing 94.4% sensitivity of the ColoSense RNA test for detecting colorectal cancers and calling it the highest reported sensitivity for a non-invasive CRC

[6] When first published, the *JAMA* paper contained a typographical error in reporting this figure; the figure was subsequently corrected.

screening test. FAC ¶ 181; *see* FAC, Ex. D at 1763. Exact does not deny that this statement is literally true: 94.4% sensitivity is indisputably higher than the reported sensitivity of any other available non-invasive test. Exact bases its claim on the assertion that Geneoscopy's statements falsely implied a "head-to-head" study of ColoSense and Cologuard. But in none of them did Geneoscopy refer to any head-to-head testing or even mention Cologuard or Exact. Moreover, the *JAMA* Report expressly acknowledges that Geneoscopy's study did ***not*** involve a "head-to-head performance comparison with other noninvasive molecular tests." FAC, Ex. D at 1764. Exact cannot plausibly allege that the alleged statements were false and misleading.[7]

Alleged deception. Doctors are the only class of consumers for these products who are a plausible target audience for the types of materials at issue.[8] And Exact's conclusory assertion of deception (Opp. 18) cannot create a question of fact as to whether physicians are likely to be deceived by short summaries of scientific studies. Physicians are well-equipped to read and digest scientific literature. This is not a question of fact, but common knowledge, and courts can take judicial notice of "matters of common knowledge." *Zavala v. Wal-Mart Stores Inc.*, 691 F.3d 527, 546 (3d Cir. 2012). No physician reading the challenged statements would be deceived by a lack of detail that is obtainable in the study itself, or into believing the study had included a head-to-head comparison with Cologuard.

Exact remains unable to identify any alleged deception other than a statement by an independent third-party media outlet, which reviewed more than just Geneoscopy's statements

[7] Exact's reliance on *Eastman Chemical Co. v. PlastiPure, Inc.*, 775 F.3d 230 (5th Cir. 2014), is misplaced. In that case, plaintiff attacked defendant's statements in a commercial brochure distributed at trade shows that specifically referenced plaintiff's product when the underlying study made no reference to it and had not been published in a peer-reviewed journal. *Id*. at 233.
[8] Exact is not entitled to any presumption of deception here given that it has at best alleged that certain statements are misleading, not false. *Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., Inc*., 19 F.3d 125, 130 (3d Cir. 1994).

and reached its own conclusions. Opening Br. 17-18. And Exact admits that this allegation relates only to deception of "others," rather than deception of relevant consumers, which is not relevant to the Lanham Act. *See* Opp. 18-19. Because Exact's allegations of deception are unsupported by a single relevant fact, its Lanham Act claim must be dismissed.

Materiality and harm. Finally, Exact has not plausibly alleged that the accused statements are material or are likely to cause economic harm to Exact. Exact does not allege that it has experienced any decline in sales due to consumers holding back from purchasing Cologuard or due to an adverse impact on Exact's reputation. Nor does Exact plausibly allege that the lack of detail in Geneoscopy's brief summaries of its pivotal study could influence a physician's choice of product; any physician who might consider the underlying detail material could easily find and review it. Exact's rote allegation that Geneoscopy's statements "are likely to affect purchasing decisions," without more, does not satisfy either the materiality or harm element of a Lanham Act claim.

F. Exact's State Law Claims Should Be Dismissed.

Finally, Exact's state and common law claims, which it defends in cursory fashion, must be dismissed for the reasons stated above and in Geneoscopy's Opening Brief.

CONCLUSION

The Court should dismiss the First Amended Complaint in its entirety.

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